



510(K) Summary

510(k) Number: K072248

NOV 09 2007

Date Prepared

October 11, 2007

Submitter Information

Submitter's Name/ Address: Enpath Medical, Inc.
2300 Berkshire Lane North
Minneapolis, MN 55441

Establishment Registration: 2183787

Contact Person: Patrice Stromberg
Principal Regulatory Affairs Specialist
(763) 951-8181 phone
(763) 559-0148 fax
pstromberg@enpathmed.com

Device Information

Trade Name: ViaPeel™ Peelable Introducer
Classification Name: Introducer, Catheter
Product Code: DYB
Regulation: Class II, 21 CFR 870.1340
Panel: Cardiovascular

Performance Standards

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Device

Enpath Medical, Inc. ViaSeal Valved Peelable Introducer (K063182)

Device Description

The ViaPeel Peelable Introducer will be available in 3.5F through 7F (micro), and 7F (macro) in lengths of 5cm or 10cm. The sheath handles are color coded for identification of French size. The locking configuration has been modified on the sheath and dilator to an annular snap fit. The dilator will lock into the hub without the use of a rotating collar allowing the user to lock and secure the dilator to the sheath.

Indications for Use

The ViaPeel™ Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Summary of Non-Clinical Testing

Performance Testing: The performance testing for this device included testing to verify that the device functions in a safe and effective manner. The performance testing included the device specifications, functional and dimensional testing of the ViaPeel Peelable Introducer and other testing as applicable to the device. Test results verify that the device performs per specification requirements and is equivalent to the predicate device without creating additional risk to the patient or user.

Biocompatibility Testing: The material in the components used to create the ViaPeel Peelable Introducer has been demonstrated to be biocompatible through biocompatibility testing.

Summary of Clinical Testing

No clinical evaluations of this product have been performed.

Statement of Equivalence

Through the data and information presented, Enpath Medical, Inc. considers the ViaPeel Peelable Introducer to be substantially equivalent to the cleared Enpath Medical ViaSeal Valved Peelable Introducers based on a comparison of the indications for use and the technological characteristics. The testing performed confirms that the ViaPeel Peelable Introducer will perform as intended.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 09 2007

Enpath Medical, Inc.
c/o Ms. Patrice Stromberg, RAC
2300 Berkshire Lane North
Minneapolis, MN 55441

Re: K072248

Trade/Device Name: ViaPeeTM Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: October 11, 2007
Received: October 12, 2007

Dear Ms. Stromberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman

B Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K072248

Device Name: ViaPeeTM Peelable Introducer

Indications for Use:

The ViaPeeTM Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Veltman
(Division Sign-Off)
Division of Cardiovascular Devices

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